DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-1254]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Communities Organized to Prevent Arboviruses: Assessment of Knowledge, Attitudes, and Vector Control Practices and Sero-Prevalence and Incidence of Arboviral Infection in Ponce, Puerto Rico (COPA Study), to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on [insert November 22, 2021] to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Communities Organized to Prevent Arboviruses: Assessment of Knowledge, Attitudes, and Vector Control Practices and Sero-Prevalence and Incidence of Arboviral Infection in Ponce, Puerto Rico (COPA Study) (OMB Control No. 0920-1254) – Reinstatement with Change – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The four viruses that cause dengue are transmitted by *Aedes* species mosquitoes and were introduced to the Americas over the past several hundred years where they have since become endemic. Puerto Rico, a Caribbean island and U.S. commonwealth, has the highest burden of dengue virus in the U.S., and recent years have seen the emergence of two epidemic arthropod-borne viruses (arboviruses) also transmitted by *Aedes* mosquitoes. Chikungunya virus was introduced into the Caribbean in late 2013 and caused large epidemics of fever with severe joint pain throughout the Caribbean and Americas in 2014. Zika virus, the first arbovirus that can also be transmitted through sexual contact, was first detected in the Americas in 2014 and has been associated with devastating birth defects and Guillain-Barre syndrome. Yellow fever virus has recently caused large outbreaks in Brazil, and

there is risk of importation to Puerto Rico and other counties in the Americas.

The public health response to the spread of these arboviruses throughout the tropics, where their mosquito vectors thrive, has been hampered by a lack of sustainable and effective interventions to prevent infection with any of these arboviruses at the community level. Moreover, the rapid speed with which new arboviruses spread generally does not provide the time needed to plan and implement community-level interventions to decrease viral transmission. Although several candidate vaccines for chikungunya and Zika viruses are currently in clinical development, none are yet available. A dengue vaccine was recently recommended for children 9-16 years old with previous dengue infection and living in dengue-endemic parts of the United States. However, this will only benefit a small proportion of the population at risk for dengue infection.

The purpose of the Communities Organized to Prevent Arboviruses (COPA) project is to measure the incidence of arboviral infections and assess suitability, acceptability, and impact of community-level mosquito control interventions in 38 communities in southern Puerto Rico. The study investigators have prior experience working in these communities; however, there is minimal available information regarding the prevalence or incidence of infection with tropical arboviruses, density of Ae. aegypti mosquitos, and community members' knowledge, attitudes, and behaviors for avoiding mosquito bites. This

information is needed to inform decision-making regarding the location, design, and content of mosquito control interventions to be implemented, as well as to evaluate their effectiveness in reducing the arbovirus burden. Additionally, the COPA project can act as a research platform to assess acceptability of arbovirus vaccines and other individual level prevention measures in Puerto Rico and provide community-level data on emerging diseases, including novel coronavirus 2019 (COVID-19). We will collect demographic information (e.g., age, sex, duration of time residing in Puerto Rico), travel history, and information on recent illnesses from all participants via household (and individual) questionnaires. Parents or guardians will serve as proxy respondents for children aged <7 years. The questionnaires will be administered after written consent and written or verbal assent (for minors) from those present in the household at the time of the visit. GPS coordinates will also be collected for each household visited to later assess for potential clustering of arboviral infections within communities. We will ask participants if they have been ill with arbovirus- or COVID-19-like illness (i.e., fever, rash, cough, sore throat, difficulty breathing, diarrhea, body pain, or loss of taste/smell) in the past week and year. If so, we will collect details on the symptoms experienced during their illness. Questionnaire administration and study participation will be limited to residents from the 38 communities in Ponce. Being a resident is defined by having slept in the house for at least

four of the past seven nights. At the time of the questionnaire administration, ~15 mL of blood will be collected to conduct serological testing of arboviruses for a sero-survey. If the participant has COVID-19-like symptoms, an anterior nasal swab will also be collected.

The questionnaire section will vary depending on the age of each participant. The Household questionnaire will be administered to one household representative in each home with one or more COPA participants. This questionnaire collects information on household composition, characteristics, and use of chemical insecticides and other preventive practices. The household representative should be 21 years or older or an emancipated minor. If all eligible household members are unemancipated minors, a household member over the age of 50 may act as household representative and complete this section of the survey only. A minor residing without an adult in the household may participate and act as a household representative if they have parent or legal guardian consent to do so.

The Individual questionnaire will be administered to all participants to collect individual-level socio-demographic information. This questionnaire will collect information on past illnesses and health seeking behaviors, identify the main healthcare facilities used in the area, and estimate costs associated with acute febrile illness. Questions related to COVID-19 vaccine uptake, illness, and diagnosis are also included to describe and estimate the number of previous SARS-

CoV-2 infections and evaluate the success of ongoing COVID-19 vaccination efforts in these communities.

The mobility questionnaire will be administered to all participants to assess general individual-level mobility patterns, including time spent in and outside of the home each week. We will ask participants about the location and characteristics of places where they spend more than five hours a week to assess potential arboviral exposures outside of the home.

The assessment of Knowledge, Attitudes, and Practices (KAP) questionnaire will be administered to participants 14-50 years old to collect information on knowledge, perceptions of risk and prevention measures, and experience with dengue and COVID-19. This data will be used to understand how community members view arboviral diseases and COVID-19 and how these perceptions relate to experience and willingness to adopt individual and community-level prevention measures. Questions related to general perceptions and confidence in vaccines will be asked to see how these relate to intentions to vaccinate against dengue and COVID-19.

A Vector Control questionnaire will be administered to all household representatives to evaluate knowledge and acceptability of several mosquito control methods. This information will be shared with local governments and vector control agencies to inform selection and implementation of potential mosquito control interventions in the region.

An Acute Illness Surveillance (AIS) project component is being implemented to better identify and assess the incidence of arboviral disease and COVID-19 among COPA participants. This additional weekly activity will use an automated text-messaging system to ask COPA household representatives and other household adults who consent to receive text messages if any COPA participants in the household have experienced fever or other COVID-like symptoms in the past seven days. Project staff will contact households in which one or more participants reported symptoms to schedule an appointment to collect samples for arbovirus and SARS-CoV-2 molecular testing and to administer a AIS questionnaire about symptoms, exposure and health seeking behaviors. From previous febrile surveillance studies, we expect approximately 40% of household adults will respond to text messages each week and 10% of COPA participants will report acute symptoms and agree to a sample collection visit each year. Participants with a positive SARS-CoV-2 molecular test will be contacted by phone 2-4 weeks later for a COVID-19 Case Follow-Up questionnaire on symptoms, health care seeking, potential exposures, and outcomes of SARS-CoV-2 infection. We are expecting that 20% of participants who report symptoms will have a positive COVID-19 result and respond to this follow-up questionnaire.

The central COPA questionnaires (Household, Individual, KAP, Mobility, and Vector Control) will be repeated among approximately 3,800 participants every 12 months, up to a period

of five years. The AIS and COVID-19 Follow-Up components will be renewed and modified annually as applicable according to research and funding priorities. This project will allow us to better understand the risk, perceptions, and burden of arboviral infections and COVID-19 and evaluate a community-based approach for vector control in 38 communities in Ponce, Puerto Rico. The information obtained will inform decision making regarding the location, design, content, and evaluation of future mosquito control interventions implemented in Puerto Rico. Data on incidence and perception of COVID-19 disease will also be used to inform local control programs and fill the current knowledge gaps.

CDC requests OMB approval for an estimated 4,309 annual burden hours. There is no cost to respondents other than the time needed to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Ponce residents from the 38 selected communities 21 years and older or emancipated minor	Household Representative questionnaire	2,700	1	10/60
Ponce residents	Individual questionnaire	3,800	1	20/60

from the 38 selected communities 1-50 years old				
Ponce residents from the 38 selected communities 1-50 years old	Specimen collection	3,800	1	5/60
Ponce residents from the 38 selected communities 14-50 years old	Knowledge, Attitudes, and Practices questionnaire	3,090	1	15/60
Ponce residents from the 38 selected communities 1-50 years old	Mobility questionnaire	3,800	1	10/60
Ponce residents from the 38 selected communities 21 years and older	Vector Control questionnaire	2,500	1	10/60
Ponce residents from the 38 selected communities 21 years and older	AIS text message	1,000	52	0.5/60
Ponce residents from the 38 selected communities with inclusion criteria	AIS questionnaire	380	1	8/60
Ponce residents from the 38 selected	COVID-19 Case Follow-Up questionnaire	75	1	6/60

communities with inclusion criteria that tested positive for SAR-CoV-2				

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